

REMARKS

The Office Action mailed December 30, 2005 has been received and reviewed. All pending claims stand rejected. The application is to be amended as previously set forth. Claims 19 and 20, as well as the non-elected claims have been canceled. All amendments and claim cancellations are made without prejudice or disclaimer. Among other places, support for the amendments to claim 10 may be found on page 20, line 31 to page 21, line 3, and claim 14 of the as-filed specification. Basis for new claim 31 is found in originally filed claim 13. No new matter has been entered. Reconsideration is respectfully requested.

1. Claims 10, 14, and 17-20 and 35 U.S.C. § 112, 2nd ¶

Claims 10, 14, and 17-20 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Applicants respectfully traverse these rejections.

It was thought that the terms “incapable of” in claim 10 and “the incapacity” of claim 17 are relative terms which render the claims indefinite. The terminology of “incapable of” has been removed from claim 10, thus mooted the rejection. Furthermore, the term “incapacity” is described on page 14, line 37 to page 15, line 1 of the as-filed application, wherein it is stated that “incapable of growing herein means that the isolate in question is not or [is] only [a] little capable to infect, multiply or be released for further replication.” It should be clear to one of skill in the art of vaccine production that when a virus is incapable of growing in a certain cell, it is of little use to try to replicate the virus in that cell. Therefore, applicants respectfully traverse the rejection, and submit that the specification does provide a standard for ascertaining the requisite degree, which would allow one of ordinary skill in the art to be apprised of the invention’s scope.

Claim 10 was further thought vague and indefinite because the terminology “a nucleic acid comprising an IBDV genome at least partly derived from IBDV” was not believed to define the metes and the bounds of what specific part(s) of the IBDV genome are to be excluded or included from the claim language. The rejected terminology has been removed from claim 10, thus mooted the rejection.

It was further thought that the term “to substantially be propagated” of claim 17 was indefinite. The terminology has been amended in an effort to overcome the rejection.

It was further thought that insufficient antecedent basis existed for “one first cell” in claim 14 as it depends from claim 13. It was further thought that the phrase “such as” renders the claim indefinite because it is unclear whether the language following the phrase is part of the claimed invention. Appropriate correction has been made.

It was further thought that there is insufficient antecedent basis in claim 18 for “one permissive second cell” as it depends from claim 17. Appropriate correction has been made.

It was further thought that there is insufficient antecedent basis in claim 19 for “said rIBDV” as it depends from claim 18. Claim 19 has been canceled, thus mooting the rejection.

Regarding claim 20, it was further thought that it is not clear from “said nucleic acid encodes at least a functional part of protein VP2” what the function is and which part of VP2 protein is included in the claim. Claim 20 has been canceled, thus mooting the rejection.

It was further thought that claim 21 is indefinite because it depends from narrower claims 20 and 19 and due to the broader recitation of a nucleic acid derived from a serotype II IBDV. Claim 21 has been amended to depend from independent claim 10.

In view of the foregoing, the rejections should be withdrawn.

2. Claims 10 and 12-22 and 35 U.S.C. § 112, 1st ¶

Claims 10 and 12-22 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse these rejections.

Specifically, it was thought that the claims are drawn to a method for obtaining an infectious recombinant IBDV (rIBDV) incapable of growing on a non-bursa cell-derived cell. It was thought that the scope of claim 10 encompasses all rIBDVs that are incapable of growing on a non-bursa derived cell. It was suggested that it has been reported that some field isolates of serotype I IBDV strains (vvIBDV) fail to become adapted to cell culture *in vitro* (Mundt, 1999), although they can replicate in bursa lymphoid cells *in vivo*. It was suggested that applicants disclose a few field isolates in the specification, however, applicants have not disclosed sufficient species of rIBDVs to support the broadly claimed method for obtaining a genus of all IBDVs that

are incapable of growing on a non-bursa derived cell. It was thought that while the skilled artisan would reasonably conclude applicants were in possession of a method of obtaining a few field strains of rIBDV, allegedly no indication existed that applicants were in possession of a method for obtaining all rIBDVs that are incapable of growing in a non-bursa cell as broadly claimed. The remaining claims have been further directed to methods of obtaining vvIBDV strains, which should overcome the rejection.

3. Claims 10 and 12-22 and 35 U.S.C. § 103(a)

Claims 10 and 12-22 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Vakharia *et al.* (U.S. Patent 5,871,744) (hereinafter “Vakharia”), Mundt (1999), and Muller *et al.* (1982) (hereinafter “Muller”). Applicants respectfully traverse these rejections.

The prior art teaches that very virulent IBDV strains cannot be propagated in cell culture on cells that are of non-Bursal origin without losing their very virulent nature (specification page 6, line 33 to page 7, line 5). Adaptation of these virus strains to cells of non-Bursal origin, such as CEF cells or QM cells, changes the very virulent nature of the vvIBDV strain to a less virulent strain (Specification, page 7, lines 2-18 and page 12, line 36 to page 13, line 3).

It is in the art that transfecting cells with cDNA is performed on cell cultures of cells of non-Bursal origin like for example CEF cells or VERO cells or QM cells (Vakharia). Vakharia even combines the VP2 of CEF adapted IBDV with other strains to make sure that the chimeric virus is propagated on the CEF cell culture. Therefore, recombinant IBDV strains produced in cell cultures are adapted and less virulent. Mundt also used a propagation step with CEO cell cultures.

It is a contribution of the present invention that recovery of truly very virulent IBDV progeny virus from cell culture cells such as CEF or VERO or QM cells is made possible by transferring supernatant of the transfected CEF, VERO, or QM cells to cells of Bursal origin for propagation. The claimed method enables, for the first time, the recovery of recombinant very virulent IBDV. The invention further provides methods to modify the virulence of the vvIBDV without affecting the VP2 region, *i.e.*, without adapting the virus to non-Bursal cells such as CEF, VERO, or QM cells.

None of the cited references discloses or even hints at the combined method of transfection of vvIBDV-non-permissive cells with vvIBDV genome and subsequent transfer of progeny virus to vvIBDV-permissive cells for propagation. Therefore, a skilled person with knowledge of the prior art would not and could not achieve the presently claimed method.

In view of the foregoing, it is respectfully submitted that the obviousness rejections should be withdrawn.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Allen C. Turner
Registration No. 33,041
Attorney for Applicants
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

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